

## REMARKS

Claims 1 - 8 are pending in the present application. The Examiner rejects Claims 1 - 8 under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the written description requirement.

In the notice mailed October 5, 2007, the Examiner indicates that Applicant's representative failed to realize that the subject of claim 8 was allowable. First, the initial response did recognize this as evidenced by the following statement "The Examiner's has failed to address the information presented in the Comer Declaration and has instead has just made the conclusory statement that the previous arguments are only persuasive to show that claim 8 is allowable." As explained in detail below, Applicants believe claims of a broader scope are allowable and do not wish to limit the claims to the promoters listed in claim 8 at this point.

The Examiner also states that the applicants failed to respond to the "reach through" argument. The Examiner's "reach though" argument is part of the written description rejection, which Applicants addressed in detail. The Examiner cites no support for the "reach though" argument nor does he provide any indication that this is a proper grounds for supporting a written description rejection. The claims would only be "reach through" claims if they were directed to compositions, for example, inhibiting the cox2 pathway as in *Univ. Rochester v. Seale & Co.*, Fed. Cir. 2004. The present claims are to assay methods and thus are not "reach through" claims to compositions as addressed by the court in *Univ. Rochester*.

In the notice mailed 10/5/07, the Examiner further states "Applicant continues to reply [sic] upon a declaration wherein the evidence submitted in the declaration is in the form of unsubmitted articles." The Applicants have attached the references cited in the Declaration of Dr. Comer to this communication. As such, the Applicants submit that the response is responsive and respectfully request that the Examiner consider the Applicants' response.

### **The Claims Comply with the Written Description Requirement**

In the previous response, Applicants amended the claims to specify that the irritant

responsive reporter gene construct comprises a promoter from an irritant responsive gene operably linked to a reporter gene. The Examiner states that the term “irritant responsive gene” encompasses “unknowns.” Office Action, p. 4. The Examiner further argues that the disclosure of two genes as being “irritant responsive” is “insufficient to describe an entire genus.” Id. The Examiner has failed to address the pending rejection to the amended claims. The current claims are not drawn solely to an irritant responsive gene, and instead further define what is meant by that term – a construct that comprises a promoter from an irritant responsive gene operably linked to a reporter gene. The Examiner has failed to provide an analysis of whether there is written description for a promoter from an irritant responsive gene operably linked to a reporter gene and has failed to rebut the previous arguments of Applicants and the information contained in the Comer declaration (filed 7/5/05). The Examiner’s has failed to address the information presented in the Comer Declaration and has instead has just made the conclusory statement that the previous arguments are only persuasive to show that claim 8 is allowable. There is no discussion of the fact that other irritant responsive genes and promoters were known in the art and could be used and those of skill in the art could identify other irritant responsive genes.

Instead of responding to the factual information presented in the Comer Declaration, the Examiner continues to rely on the holding of *Eli Lilly*. Office Action p. 4. The Examiner’s attention is respectfully directed to the Federal Circuit’s recent holding in *Falkner v. Inglis*, 448 F.3d 1357; 79 U.S.P.Q.2D (BNA) 1001 (Fed. Cir. 2006). In that case, the Federal Circuit specifically held that “*Eli Lilly* does not set forth a *per se* rule that whenever a claim limitation is directed to a macromolecular sequence, the specification must always recite the gene or sequence, regardless of whether it is known in the prior art.” Id. at 1367. The Federal Circuit went on to explain that:

Thus, “[w]hen the prior art includes the nucleotide information, precedent does not set a *per se* rule that the information must be determined afresh.” Id. at 1358. Rather, we explained that:

The descriptive text needed to meet these requirements varies with the nature and scope of the invention at issue, and with the scientific and technologic knowledge already in existence. The law must be applied to each invention that enters the patent process, for each patented advance is novel in relation to the state of the science. Since the law is applied to each invention in view of the state of relevant knowledge, its application will vary with differences in the state of knowledge in the field and differences in the predictability of the science.  
Id. at 1357.

Indeed, a requirement that patentees recite known DNA structures, if one existed, would serve no goal of the written description requirement. It would neither enforce the quid pro quo between the patentee and the public by forcing the disclosure of new information, nor would it be necessary to demonstrate to a person of ordinary skill in the art that the patentee was in possession of the claimed invention. As we stated in Capon, "[t]he 'written description' requirement states that the patentee must describe the invention; it does not state that every invention must be described in the same way. As each field evolves, the balance also evolves between what is known and what is added by each inventive contribution." Id. at 1358. Indeed, the forced recitation of known sequences in patent disclosures would only add unnecessary bulk to the specification.

Id. at 1367-68. The Federal Circuit then specifically held that "where, as in this case, accessible literature sources clearly provided, as of the relevant date, genes and their nucleotide sequences (here "essential genes"), satisfaction of the written description requirement does not require either the recitation or incorporation by reference (where permitted) of such genes and sequences." Id. In the instant case, sequences for both defensins and regulatory elements within the claims were known in the art and reference sequences were described in the specification (see, e.g., p. 36-39) and identified in the claims and generic support for the claims has been provided. That is all the written description that is needed. Applicants have gone far beyond the requirements of Falkner and recited the known sequence structures in the specification.

Moreover, as held in Falkner, compliance with the written description requirement must be determined an analysis of what one of skill in the art would have thought as of the filing date of the application. The Comer Declaration is directly relevant to this issue. The Comer Declaration establishes that other irritant responsive genes and promoters were known in the art of the filing date of the application and that one of skill in the art could identify additional irritant responsive reporter genes. The Examiner has not rebutted this evidence of record. This application was filed in 2002 and claims priority to an application filed in 2001. As of the priority date, one of skill in the art would have recognized that the genes and regulatory elements disclosed in the specification and known in the art provide a genus supporting the claims. As such, one of skill in the art would conclude that the Inventors were in possession of the necessary common attributes possessed by the members of the genus, and therefore the instant specification meets the written description requirement for these claims. The Applicants respectfully request these rejections be withdrawn.

The Federal Circuit has stated time and time again that rebuttal evidence of one skilled in the art cannot be dismissed by the Office without consideration. The Examiner must respond to all of the arguments and evidence presented by Applicants. The MPEP states that:

**Office personnel should consider all rebuttal arguments and evidence presented by applicants. . . .** *In re Beattie*, 974 F.2d 1309, 1313, 24 USPQ2d 1040, 1042-43 (Fed. Cir. 1992). . . . **Office personnel should avoid giving evidence no weight**, except in rare circumstances. *Id. See also In re Alton*, 76 F.3d 1168, 1174-75, 37 USPQ2d 1578, 1582-83 (Fed. Cir. 1996).

In *In re Alton*, the applicants submitted a declaration in order to rebut a *prima facie* case of inadequate written description by the Board of Appeals in an earlier appeal. *Id.* at 1173. Instead of addressing the arguments presented in the declaration, the Examiner dismissed the declaration as opinion evidence that was entitled to little weight. *Id.* at 1173-745. The Federal Circuit remanded the case to the Board, holding that the Board committed error in both viewing the declaration as opinion evidence and dismissing the declaration "without an adequate explanation of why the declaration failed to rebut the Board's *prima facie* case" of unpatentability. *Id.* at 1174. These bases for reversal were independent. With respect to failure to provide an adequate explanation of why the declaration failed to rebut the *prima facie* case, the Federal Circuit found that:

In sum, the examiner dismissed the Wall declaration and provided only conclusory statements as to why the declaration did not show that a person skilled in the art would realize that Alton had possession of the claimed subject matter in 1983.

*Id.* at 1176. In particular, the Federal Circuit held that the examiner failed to address specific points made in the declaration concerning modifications of the amino acids sequence of protein. *Id.*

*In re Alton* is directly applicable to the present facts. Instead of addressing the arguments presented in the Comer Declaration, the Office has provided only conclusory statements and failed to address the particular evidence offered in the Declaration. As a result, Applicants respectfully request that the Examiner reconsider the evidence offered in the Comer Declaration.

**Attorney Docket No.:**  
**STRATA-06948**

**CONCLUSION**

All grounds of rejection and objection of the Office Action of October 12, 2006 and Notice of Noncompliance sent October 5, 2007 having been addressed, reconsideration of the application is respectfully requested. It is respectfully submitted that the invention as claimed fully meets all requirements and that the claims are worthy of allowance. Should the Examiner believe that a telephone interview would aid in the prosecution of this application, Applicant encourages the Examiner to call the undersigned collect at (608) 218-6900.

Dated: 1/7/08

/Tanya A. Arenson/

Tanya A Arenson  
Registration No. 47,391

CASIMIR JONES SC  
440 Science Dr. Ste. 203  
Madison WI 53711  
608.218.6900